

administered claims is often handled by humans, and on a more individualized basis. For example, a specialty pharmacy reference source states:

“Physician relationships – essential though they are – place obstacles to efficient claims processing and reimbursement of specialty pharmaceuticals. Unlike oral medications that use electronic claims adjudication, injectable drugs are often reimbursed through claims payment using human coding processes (J-codes, etc.). Even in systems where injectable drugs are adjudicated through the specialty distributor process, most physicians maintain their paper reimbursement processes. In this reimbursement process, the human adjudicator factor may result in substantial overpayment for certain injectable medications.”²⁵³

An industry trade publication reporting on a 2004 forum in which major challenges facing the management of specialty drugs were discussed, noted the following strategy for data management:

“Improved data management. With about 70% of specialty pharmacy still reimbursed as a medical benefit and many plans managing 10 to 15 different specialty pharmacy vendors, experts agreed that tracking patient data is nearly impossible. These issues make it difficult to tell payers where their money is going, said Lotvin. Medco Health is now attempting to integrate its medical specialty data with its pharmacy data by using a database to ‘crosswalk’ the J-code to the National Drug Code (NDC). Once Medco Health integrates that information on the PBM side, it can apply pricing disciplines and utilization management, and identify duplicate claims, said Russek.”²⁵⁴

In a different industry publication, an executive at AdvancePCS reports that in his experience health plans become “flabbergasted at what they’ve been paying for years on drugs” on the medical side because of dramatic price markups.²⁵⁵

191. In summary, when medical benefit expenditure data are poorly monitored and “tracking patient data is nearly impossible”, and when this is widely known, possibilities for

²⁵³ AIS [2003], *supra*, p. 73.

²⁵⁴ “Specialty Benefit Management Is Next Step In Biotech Market Evolution, Experts Say”, reprinted from the June 11, 2004 issue of Drug Cost Management Report, p. 3. Available online at <http://www.aishealth.com/DrugCosts/specialty/DCMRSpecialtyBenefitBiotec.html>, last accessed 12/29/04. Allan Lotvin, M.D., is President of Specialty Pharmacy Services at Medco Health Solutions, Inc. (p. 1). Steve Russek is Medco Health’s Vice President, Product Development, Specialty Pharmacy (p. 2).

²⁵⁵ “AdvancePCS Views Its Specialty Rx as Complementary to Caremark’s Approach,” reprinted from the January 2004 issue of *Specialty Pharmacy News*, p. 4. Available online at <http://www.aishealth.com/DrugCosts/specialty/SPNAdvancePCSComplementCaremark.html>, last accessed 12/29/2004.

mischievous and abuse arise. That appears to be the case for physician-administered drugs adjudicated under the medical benefit.

192. A fourth and related distinguishing feature of physician-administered vs. self-administered drugs concerns how the utilization and pricing of distinct products are tracked. Stephen W. Schondelmeyer and Marian V. Wrobel have described the detailed 11-digit coding system for self-administered drugs:

“Every firm that markets a prescription drug in the United States must register with the FDA to obtain a unique national drug code (NDC) number (11-digit) for each product marketed. The first part of the NDC, the labeler code (5-digits), uniquely identifies the firm marketing the drug product. The second segment, the product code (4-digits), identifies a specific strength, dosage form, and formulation for a given drug product. The third segment, the package code (2-digits), identifies package sizes and package types (e.g., bulk, unit dose, or unit of use). Both the product and package codes are assigned by the firm and not by the FDA.

Manufacturers or marketers, who want to be assured that the Medicaid program will cover their drug products, must sign a national drug rebate agreement with the Secretary of the Department of Health and Human Services in order for states to receive federal funding for outpatient drugs dispensed to Medicaid patients.”²⁵⁶

PBMs utilize these 11-digit NDC codes to monitor in real time the dispensing activities of network retail and mail order pharmacies, and immediately alert the dispenser if there are any suspected adverse interaction issues with other self-administered drugs being taken concomitantly, or with payment problems regarding adjudication of the claim. This 11-digit NDC coding system therefore facilitates the efficient electronic monitoring and processing of self-administered prescription drug purchases at the point of service.

193. In contrast, the Healthcare Common Procedure Coding System (HCPCS) established by CMS is based on a number of different 5-digit (one letter plus four numerical digits) codes, commonly known as J-codes and Q-codes. Providers use HCPCS J-codes to bill

²⁵⁶ Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Introduction, Final Report, Contract #500-00-0049, Task Order 1, August 30, 2004, Cambridge, MA: Abt Associates Inc, pp. 9-10.

the Medicaid program for injectable prescription drugs, including cancer drugs.²⁵⁷ Examples of the 5-digit J-codes are J1440 for Neupogen, J1950 for Lupron, and J9202 for Zoladex. Another 5-digit J-code is J2941, which covers a host of human growth factor products, having brand names Genotropin, Genotropin Miniquick, Humatrope, Norditropin, Nutropin, NutropinAQ, Nutropin Depot, Salzen and Serostim.²⁵⁸ An example of a 5-digit Q-code is Q4055, which is the new CMS HCPCS code for erythropoietin (“EPO”) administered to patients with end stage renal disease.²⁵⁹

194. Unlike the 11-digit NDC codes for self-administered drugs, the 5-digit J-codes for physician-administered drugs are not unique for product size, packaging or dose, implying that a single billable J-code can be composed of numerous distinct NDC codes, thereby obfuscating not only which particular NDC product was actually administered, but how many units were utilized. This creates significant difficulties in tracking physician-administered drug utilization and unit prices. For example, an industry trade publication called Managed Care Week compared the NDC vs. J-codes, and noted implications for reliable monitoring of prices and utilization:

“Retail pharmacy systems already have a lot of checks and balances that ensure, for example, that medications are priced correctly and are on the managed care plan’s formulary, she says. By comparison, pricing of specialty pharmacy medications is much less controlled in the medical claims system. That makes it much more difficult for managed care companies to know how much they’re spending and on which drugs.

Part of the problem is the ‘J-codes’ established by CMS to identify certain drugs and other items. These codes aren’t unique for product size, packaging or dose, so it’s impossible to tell from the claim how much of the medication was administered. Secondly, there are many injectable products for which no J-code exists, so claims are submitted using a miscellaneous J-code instead . Because of the lack of detail in J-

²⁵⁷ Letter from Dennis G. Smith, Director for Center for Medicaid and State Operations addressed to State Medical Directors, dated March 14, 2003. Available online at <http://www.cms.hhs.gov/states/letters/smd031403.pdf>, last accessed 2/7/05.

²⁵⁸ AIS [2003], *supra*, pp. 91-92, Figure 5-4, “Specialty Drugs Available Through McKesson for HMO Blue Texas Patients”.

²⁵⁹ “Clarification of Epoetin Alfa (EPO) Billing Procedures and Codes in ESRD”, available online at <http://www.cms.hhs.gov/medlearn/matters/mmarticles/2004/SE0406.pdf>, last accessed 2/7/05.

codes, health plans could be at the mercy of the provider to get a fair price for a given drug.”²⁶⁰

Moreover, since the J-codes are commonly used when providers bill Medicare or other commercial carriers, unlike the real time NDC-code based transactions monitoring by PBMs, with J-codes the monitoring is *ex post*. As one industry analyst put it, “With the J-code, most of the billing is retrospective, and you find out about issues 60 to 90 days too late, after the event occurs.”²⁶¹

195. Defendants’ Expert Steven J. Young acknowledges difficulties that arise when J-codes encompass multiple NDC codes for branded single source physician-administered drugs, as well as from the fact that a single J-code typically covers all NDCs from various generic manufacturers selling a multisource physician-administered drug.²⁶² He also points out that relative to the highly automated processing of claims based on NDCs and their links to AWP, “The claim processing for J-code claims, however, requires a relatively manual process to determine the quantity of the drug administered and then determine the appropriate reimbursement level for that drug.”²⁶³ One industry observer estimated that the cost of electronically processing a self-administered drug claim typically runs between 25 and 50 cents, versus about \$45 for staff to handle a typical paper-based medical claim.²⁶⁴

²⁶⁰ “To Overhaul Specialty Pharmacy Practices, First Step In to Identify Current Policies”, reprinted from the 4/17/03 issue of Managed Care Week, p. 2. The “she” to which the article refers is “Kim McDonough, Pharm.D., founder of North Kingstown, R.I.-based pharmacy consulting firm Advanced Pharmacy Concepts” (p. 1). Available online at <http://www.aishealth.com/DrugCosts/MCWPharmoverhaul.html>, last accessed 12/28/04.

²⁶¹ “AdvancePCS Views Its Specialty Rx as Complementary to Caremark’s Approach”, reprinted from the January 2004 issue of *Specialty Pharmacy News*, quoting Mike Ellis, senior vice president of specialty pharmacy for AdvancePCS, p. 3. Available online at <http://www.aishealth.com/DrugCosts/specialty/SPNAdvancePCSComplementCaremark.html>, last accessed 12/29/04.

²⁶² *Sur-Reply of Steven J. Young in Opposition to the Plaintiff’s Motion for Class Certification*, January 20, 2005, pp. 22-26, Paragraphs 36-45..

²⁶³ *Sur-Reply of Steven J. Young in Opposition to the Plaintiff’s Motion for Class Certification*, January 20, 2005, p. 23, Paragraph 39.

²⁶⁴ “Advance PCS Views Its Specialty Rx as Complementary to Caremark’s Approach,” reprinted from the January 2004 issue of *Specialty Pharmacy News*, attributing remarks to Mike Ellis, senior vice president of specialty

196. Plaintiff's Expert Dr. Raymond Hartman also acknowledges the lack of specificity in the J- and Q-coding detail. For example, in a footnote Dr. Hartman states:

"A J-code is a special code developed by the Health Care Financing Administration (now CMS) for Medicare reimbursement purposes that is now frequently used by hospitals and physician offices to identify primarily injectable drugs administered to a patient. Typically there is only one J-code for a particular drug that may include multiple NDCs. A Q-code is essentially a temporary code assigned by CMS until a permanent J-code is assigned."²⁶⁵

In referencing Defendants' Expert Steven J. Young's use of several J-codes having multiple NDCs, Dr. Hartman notes that over the relevant time period, Procrit had a single Q-code but eleven NDCs being sold and reimbursed, and that the five-digit codes for Albuterol, Imitrex and Blenoxane each had four NDCs being sold.²⁶⁶ This leads Dr. Hartman to attack the credibility and usefulness of analyses prepared by Defendants' Experts Steven J. Young and Dr. Eric M. Gaier: "I conclude that the analyses by these experts of physician-administered drugs for J-codes with multiple NDCs are of little or no evidentiary value."²⁶⁷ Defendants' Expert Steven J. Young then points out that if Dr. Hartman is correct, this very critique undermines Dr. Hartman's ability to conduct reliably his analysis of physician-administered drugs without undertaking significant individual inquiry.²⁶⁸

197. This raises the issue of how easy and reliable it is to crosswalk from J-code to NDC-code claims. A March 14, 2003 letter from Dennis G. Smith, Director of the Center for Medicaid and State Operations, summarizes the process as follows:

pharmacy for AdvancePCS, p. 4. Available online at <http://www.aishealth.com/DrugCosts/specialty/SPNAdvancePCSComplementCaremark.html>, last accessed 12/29/04.

²⁶⁵ *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, fn. 59, p. 37.

²⁶⁶ *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, fn. 60, p. 38.

²⁶⁷ *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, p. 38.

²⁶⁸ *Sur-Reply of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, January 20, 2005, p. 4.

“The process of crosswalking J-codes and other HCPCS-coded drugs to corresponding NDCs is very simple in cases where there is a one-to-one relationship between the J-coded drug and the NDC number. It can be more labor intensive where one J-code correlates to different NDC numbers. We are aware that private contractors have developed innovative systems that crosswalk J-codes to corresponding NDCs, including doing an in-pharmacy review of claims where necessary. These systems allow states to identify NDCs for the J-codes and bill manufacturers for rebates for these drugs.”²⁶⁹

Just how labor intensive crosswalking will be, and how individualized the process will need to be in order to be reliable, particularly going back in time to the 1990s, is unclear to me at this point. This is an important issue that merits thoughtful and concise clarification by both Plaintiffs’ and Defendants’ experts.

198. What is clear, however, is that because physician-administered drugs have traditionally been reimbursed by J-code claims that often encompass a variety of distinct NDC entities, in many cases it has been difficult for healthcare organizations to monitor and observe the utilization and pricing trends underlying their expenditures on physician-administered drugs.

199. The issue of pricing transparency has been raised extensively by Plaintiffs in regard to PBMs and their management of purchases of self-administered drugs. I have dealt with that issue extensively in Section IV of this report. It is clear to me, however, that when it comes to physician-administered drugs, issues of pricing transparency become an order of magnitude larger. This creates opportunities for mischief and abuse that are very different from and much more obvious than in the case of self-administered drugs.

200. In conclusion, the continuing diverse ownership patterns of PBMs, the long series of investigations and continuing scrutiny of PBMs by various federal and state government agencies, the presence of audit privileges concerning “secret” PBM rebates as negotiable items in contracts, and the ubiquity of standardized and impersonal electronic transactions, together have

²⁶⁹ Letter from Dennis G. Smith, Director, Center for Medicaid and State Operations, dated March 14, 2003. Available online at <http://www.cms.hhs.gov/states/letters/smd031403.pdf>, last accessed 2/7/05.

exerted a market discipline on the behavior of PBMs, generating a market-determined amount of transparency, and making competition among them “vigorous” in the market for self-administered drugs, as has been stated repeatedly by the FTC. By contrast, in the market environment for physician-administered drugs, a variety of forces – the relatively small dollar amounts they involve, the ambiguity of whether the claims stem from the medical or drug component of the health benefit, the troublesome relationships with providers who act as both buyers and sellers (and prescribers and dispensers) of physician-administered drugs, and the J-code claims system that has obfuscated the utilization and pricing of individual drug products and confounded close monitoring -- have together contributed instead to a system lacking checks and balances and inviting abuse. Some of that abuse has already been uncovered in this Court and elsewhere.

VI. INITIAL OBSERVATIONS ON THE METHODOLOGY PROPOSED BY DR. HARTMAN, AND ON ISSUES REGARDING CLASS CERTIFICATION

201. Numerous observers, as well as participants in this litigation, have commented on how complex and complicated are the relationships among agents interacting in the US pharmaceutical marketplace. While that may well be true, it is useful to place today’s environment into historical perspective.

202. Recall that thirty years ago, patients actually spoke with their pharmacists, and if they had drug insurance coverage (which most did not), they carefully saved receipts from their cash/credit card prescription purchases, put them into a shoe box, and then at the end of a quarter or a year, collected the receipts, filled out forms by pencil, and sent receipts plus forms to their insurer for reimbursement. Information technology, screen monitors and modems were not to be found in this process.

203. Observers of pharmacy transactions at that time complained frequently about how widely prescription prices varied, not just among pharmacies, but even within pharmacies, depending on what pharmacist filled the prescription. For example, writing in the *Journal of the American Pharmaceutical Association* in 1973, Albert I. Wertheimer summarized his findings on intrapharmacy pricing variability for identical prescriptions dispensed in Buffalo, New York, as follows:

“It is concluded that many pharmacies all too casually calculate the charges for their services. The charge for pharmaceutical services should not depend upon which pharmacist is on duty or upon the practitioner’s mood, but rather upon sound professional and management principles. It is concluded that pharmacy managers fail to accurately convey their fee policies and techniques to their fellow pharmacists at their pharmacy and that far too little attention is paid to the effects of charge inconsistency.

The concept of usual and customary fees is dealt a bitter blow in those pharmacies where there is but one usual and customary component to prescription pricing – randomness.”²⁷⁰

Four years later, in an article entitled “The Mysteries of Prescription Pricing in Retail Pharmacies” published in the peer-reviewed journal *Medical Care*, the coauthors also report finding substantial interpharmacy price variability, as expected, but also intrapharmacy pricing heterogeneity. They also suggest a possible anti-competitive conspiracy:

“What is surprising, however, is that the data show that within a two-week period, the price of the same quantity of the same dosage form of the same drug in the same pharmacy also varies by as much as 130 percent. The findings are consistent with the hypothesis of anti-competitive pricing which, by denying consistent price information to the consumer, makes rational purchasing behavior impossible.”²⁷¹

While today’s health care markets are undoubtedly complex and perhaps even convoluted, it is worth remembering that issues involving the lack of transparency in the pricing of prescription pharmaceuticals have a considerable history in the US, as do the conspiracy theories that attempt

²⁷⁰ Albert I. Wertheimer, “Pricing Pharmaceutical Service – Art, Science or Whim,” *Journal of the American Pharmaceutical Association*, Vol. NS13, No. 1, January 1973, p. 12.

²⁷¹ S. E. Berki, J. W. Richards, and H. A. Weeks, “The Mysteries of Prescription Pricing in Retail Pharmacies,” *Medical Care*, Vol. 15, No. 3, March 1977, p. 241.

to explain them. In this context, it is somewhat ironic that Stephen Schondelmeyer and Marian V. Wrobel have commented that due to the fact that the proportion of self-pay or cash prescriptions has fallen from about 56% in 1992 to about 15%, this has “greatly reduced the pharmacy’s pricing flexibility.”²⁷²

204. I have argued at length in this report that the management and distribution of prescription drugs differs substantially and materially in the self-administered vs. physician-administered market segments. While PBMs have become involved in one way or another in almost all transactions involving self-administered drugs, their role in managing physician-administered transactions is relatively minor, although increasingly they are aligning themselves with specialty pharmacies in the physician-administered market segment. To the best of my knowledge, PBMs did not play any major role in the egregious examples of fraudulent pricing and marketing involving sales of Lupron and Zoladex to physicians. Both Lupron and Zoladex are injectable medicines. Lupron is typically administered in a physician’s office as a single intramuscular injection, frequently in the buttock, whereas Zoladex is administered subcutaneously in the upper abdominal wall using an aseptic technique under the supervision of a physician.²⁷³ It is therefore somewhat confusing and misleading when, for example, Plaintiff’s

²⁷² Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Introduction, Final Report, Contract #500-00-0049, Task Order 1, Cambridge, MA: Abt Associates Inc, August 30, 2004, p. 12.

²⁷³ Various depot formulations of Lupron are pictured on p. 337 and described on pp. 3281-3292 in *Physicians’ Desk Reference*, PDR 56 Edition 2002, Montvale NJ: Medical Economics Company; ranging in strength from 3.75 mg to 40 mg (fourth months formulation). The labeling for each of these depot administrations states “LUPRON DEPOT Must Be Administered Under The Supervision Of A Physician (p. 3283 for 3.75 mg depot, p. 3285 for 7.5 mg depot, p. 3287 for three month 11.25mg, p. 3289 for three month 22.25 mg, p. 3291 for four month 30 mg, and p. 3292 for the pediatric 7.5 mg, 11.25 mg and 15 mg formulations. Lupron is also supplied in a 2.8 ml multiple dose vial, with each 0.2 ml containing 1 mg of active ingredient (p. 3280). This formulation can be administered by a patient/parent or health care professional (p. 3281), and is pictured on p. 337. Zoladex injection is pictured on p. 306 of the same PDR 2002, and its 3.6 mg implant and three-month 10.8 mg implant formulations are described on pp. 702-708. Both dosage forms should be administered “into the upper abdominal wall using an aseptic technique under the supervision of a physician” (p. 705 for 3.6 mg implant, p. 708 for 10.8 mg implant (three-month))

Expert Dr. Raymond S. Hartman concludes that competition among PBMs is insufficient, citing as support the physician-administered Lupron scandal:

“The analyses put forward by Defendants’ experts, particularly Dr. Gaier, are flawed and insufficient to demonstrate that existing PBM competition, specifically, and provider competition, generally, were sufficient to eliminate the AWP scheme. If such competition exists, it should have been sufficient to dissipate and eliminate the significant payor injury and economic damages found and pled guilty to in the Lupron matter. It was not.”²⁷⁴

This is a massive case, and in dealing with it the distinction between self-administered and physician-administered drugs is necessary and useful.

A. Self-Administered Drugs

205. Both sides in this matter agree that in the context of self-administered drugs, PBMs play a central role; I have documented those views earlier in this report. Plaintiffs allege that competition among PBMs is not effective.²⁷⁵ The Federal Trade Commission appears to disagree. While competition among PBMs may not conform to the undergraduate microeconomics textbook example of a perfectly competitive market (in which all buyers are either fully or at least equally informed, and everyone is a price taker), federal regulatory authorities have concluded that PBM competition is “vigorous”.

206. Specifically, over the years the PBM industry has been closely monitored by the FTC (in both the Clinton and subsequent Bush administrations), and in some cases when it concluded competition might be harmed, it used its regulatory powers to intervene (e.g., to require firewalls between drug manufacturers and the PBMs they owned). As late as last year, in the context of investigating possible anticompetitive effects of horizontal consolidation among

²⁷⁴ *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, pp. 19-20.

²⁷⁵ See, for example, *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, pp. 19-20, 72-82.

two of the largest PBMs -- the Caremark/ AdvancePCS acquisition -- the FTC allowed the transaction to go forward, stating:

“We concluded that these large employers are not likely to encounter anticompetitive effects from the acquisition in light of the competition that will exist following this transaction. Competition from the remaining independent, full-service PBMs with national scope – Medco, Express Scripts, and the merged Caremark/Advance PCS {Footnote 3 Not Reproduced} – and significant additional competition from several health plans and several retail pharmacy chains offering PBM services should suffice to prevent this acquisition from giving rise to a potentially anticompetitive price increase.”²⁷⁶

“At most, the acquisition is likely to increase the bargaining power of the merged PBM and to increase its shares (and correspondingly reduce the pharmacies’ shares) of the gains flowing from contracts between the PBM and the pharmacies. It is likely that some of the PBM’s increased shares would be passed through to PBM clients {Footnote 6 Here Reproduced Next}. We anticipate that competition among PBMs will remain vigorous in the wake of the Caremark/AdvancePCS acquisition, and that this competition is likely to cause PBMs to pass on at least some of their cost savings to their customers in order to gain or retain their business.”²⁷⁷

In the context of self-administered drugs, therefore, Plaintiffs’ arguments and conclusions appear to be at variance with those of the FTC, and my own analysis discussed earlier in this report. If competition among PBMs is vigorous, even if the self-administered AWPIDs were artificially inflated, injury and damages to third party payors do not follow, particularly on a class-wide basis. Since lack of competition among PBMs is crucial to Plaintiff’s theory, this would appear to undermine their allegations, and certainly their assumption of class-wide injury and damages. Plaintiffs have not, in my judgment, addressed this issue effectively.

207. In support of their claim that competition among PBMs is not sufficient, Plaintiffs point to the facts that even as the “spread” between AWP and ASP facing retail and mail order

²⁷⁶ Statement of the Federal Trade Commission, *In the Matter of Caremark Rx, Inc./Advance PCS*, File No. 031 0239, p. 2. Available online at www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf, last accessed 1/16/05.

²⁷⁷ Statement of the Federal Trade Commission, *In the Matter of Caremark Rx, Inc./Advance PCS*, File No. 031 0239, p. 3. Available online at www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf, last accessed 1/16/05.

pharmacies for generic drugs has increased over time, the average reimbursement rates for generic self-administered drugs paid by third party payors to retailers have not fallen commensurately, implying that pharmacies have benefited and that PBMs have not been able to provide a competitive market discipline on these generic drug transactions.²⁷⁸ Plaintiffs' empirical argument that retail (and PBM mail order) "spreads" for generic self-administered drugs have grown more rapidly than have reductions in reimbursements paid by third party payors to retailers is credible. But even if true, this does not necessarily imply a lack of effective competition among PBMs.

208. As I pointed out earlier in this report, generic drug costs are typically only 10-20% of third party payor total prescription drug costs, and third party payors are understandably gratified whenever they achieve a generic for brand substitution switch. Once having achieved a cost saving from the substantial price difference between a brand and its bioequivalent generic, the third party payor (and or its PBM) understands that the additional, incremental savings it might obtain from negotiating lower generic prices with retailers are likely to be relatively small. However, even when relatively small, those incremental cost savings are present, and perhaps it is that possibility that the FTC referred to in the second paragraph of the above FTC quote when it envisaged possible increased buying power for PBMs resulting from the Caremark/AdvancePCS acquisition. The FTC footnote quoted above also suggests the FTC expected part of the lower prices obtained by PBMs in their dealings with retailers would be passed on to third party payors and their beneficiaries.

209. In summary, the Plaintiffs' theory in the context of self-administered drugs requires that competition among PBMs be insufficient to prevent injury and damages to third

²⁷⁸ See, for example, *Declaration of Raymond S. Hartman In Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, p. 13.

party payors. In my judgment Plaintiffs have not put forward a convincing argument supporting the notion that competition among PBMs is inadequate. Plaintiffs' contention is also at variance with conclusions reached by the FTC.²⁷⁹

210. There is one other matter that merits attention in this context. Even if Plaintiffs' argument concerning lack of competition among PBMs were true, to the extent they owned and operated their own PBMs (and recall that the ownership structure of the PBMs has been and continues to be very diverse), third party payors would seem to me to have benefited from the allegedly fraudulent AWP scheme, and thus they would appear to face conflicts as members of the proposed class. I will not comment on this further.

211. Issues of typicality, commonality and variability are frequently at the crux of deliberations involving class certification. Before addressing some of those issues, however, I first summarize my understanding of the methodology that Plaintiff's Expert Dr. Raymond Hartman proposes to employ in assessing class-wide liability and damages.

212. In assessing whether the proposed end-payer classes were damaged, Plaintiffs' Expert Dr. Hartman proposes first to compute the spreads between AWP and ASP "for drugs unaffected by the scheme and fraud", and then use these as "yardsticks" in comparison with spreads observed "for the drugs subject to this litigation". In cases where he determines the latter spreads are larger than the former, Dr. Hartman proposes to employ his yardsticks along with mathematical and algebraic formulae "to determine the spread that would have been used

²⁷⁹ This is not to say that PBMs are currently exempt from litigation and government investigations. See, for example, "The United States Settles Its Anti-Fraud Claims for Injunctive Relief and 20 State Attorneys General Settle Unfair Trade Practices Claims Against Medco Health Solutions: Medco to Provide Price Information to Doctors and Patients and Pay \$29 Million Plus To States in Damages, Fees, and Restitution – Federal Damages Case Continues", U. S. Department of Justice press release, April 26, 2004, available online at www.usdoj.gov/usao/pae/News/Pr/2004/apr/medcoinjunctivereliefrelease.pdf, last accessed 12/31/2004.

for the affected drugs but-for the wrongful scheme”, thereby determining “the overall class-wide injury and damage for each drug”.²⁸⁰

213. A critical component of this methodology is the comparison between the spreads achieved by AWPID “artificially inflated” drugs with those achieved by drugs “not subject to this Litigation”.²⁸¹ The choice of comparator drugs, and time periods, is important and requires considerable care, particularly in isolating the impact of the allegedly fraudulent pricing scheme. I note that the results obtained from the comparator analyses by Dr. Hartman will then become a critical part of his construction of “but for” prices for the AWPID drugs at issue.

214. There are many factors that can affect a manufacturer’s decision on how to set AWP, ASP, and therefore their difference. For self-administered single source, brand name drugs (such as those sold by competing oligopolists/monopolists, as I discussed in Section IV above), a number of factors affect not only the launch price (both AWP and ASP) of a newly FDA-approved drug, but will also affect the trajectory of pricing (both AWP and ASP) as the competitive landscape changes. Among the medical and economic factors that the literature suggests affect the price schedule of single source, brand name self-administered drugs during the product’s life cycle are the following:²⁸²

²⁸⁰ *Plaintiffs’ Memorandum In Opposition to Defendants’ Motion to Strike the Hartman Declaration*, December 17, 2004, p. 3.

²⁸¹ The words “drugs not subject to this Litigation” are taken from *Declaration of Raymond S. Hartman in Support of Plaintiffs’ Motion for Class Certification*, September 3, 2004, p. 9. Drugs not subject to this litigation could apparently include non-AWPID drugs from Defendant manufacturers, or drugs from non-Defendant manufacturers. In the same document, Dr. Hartman states on p. 9, “I have reviewed data for Defendant Drug Manufacturers’ drugs not subject to this Litigation, and I plan to review similar data for non-defendant drug manufacturers should discovery allow.”

²⁸² The literature is substantial. Some of the more well-known studies (that contain reference to many other studies) include: Richard E. Caves, Michael D. Whinston and Mark A. Hurwitz, “Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry,” *Brookings Papers: Microeconomics 1991*, Washington DC: The Brookings Institution, 1991, pp. 1-48; Z. John Lu and William S. Comanor, “Strategic Pricing of New Pharmaceuticals,” *Review of Economics and Statistics*, Vol. 80, No. 1, February 1998, pp. 108-118; Alan T. Sorensen, “Equilibrium Price Dispersion in Retail Markets for Prescription Drugs,” *Journal of Political Economy*, 108(4), August 2000, pp. 833-850; Sara Ellison, “Recent Patterns in Antibiotics Pricing,” Cambridge, MA: MIT Dept. of Economics, September 1997; Mark Duggan, “Do new prescription drugs pay for themselves? The case of second-generation

- whether the product treats an acute vs. a chronic condition (e.g., frequency of purchase);
- therapeutic class (e.g., psychotropic vs. statin);
- class of trade purchaser (e.g., chain pharmacy, mass merchant pharmacy, food and drug pharmacy, independent pharmacy, mail order pharmacy, health plan pharmacy, clinic and physicians' office, long term care pharmacy, hospital, government facilities and other);
- number of single-source brand name competitors in the same therapeutic class;
- whether any brands in the same therapeutic class are multisource, i.e. have generic competitors;
- time before expected patent expiration and initial generic entry;
- side effect, efficacy and convenience profiles relative to competitors in the class;
- substitutability with and cost of non-pharmacological treatments (e.g., psychotherapy vs. antidepressant therapy);
- substitutability with and cost of non-Rx versions (e.g., over-the-counter competition); and
- initial FDA priority designation (historically, FDA ratings of A, B or C, and more recently, standard vs. priority).

antipsychotics", *Journal of Health Economics*, 24(1), January 2005, pp. 1-31; Ernst R. Berndt, Robert S. Pindyck and Pierre Azoulay, "Consumption Externalities and Diffusion in Pharmaceutical Markets: Antiulcer Drugs", *Journal of Industrial Economics*, 51(2), June 2003, pp. 243-270; Ernst R. Berndt, Ashoke Bhattacharjya, David Mishol, Almudena Arcelus and Thomas Lasky, "An Analysis of the Diffusion of New Antidepressants: Variety, Quality, and Marketing Efforts", *The Journal of Mental Health Policy and Economics*, Vol. 5, No. 1, March 2002, pp. 3-17; Ernst R. Berndt, "Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price", *Journal of Economic Perspectives*, 16(4), Fall 2002, pp. 45-66; Ernst R. Berndt, Iain M. Cockburn and Zvi Griliches, "Pharmaceutical Innovation and Market Dynamics: Tracking Effects on Price Indexes for Antidepressant Drugs," *Brookings Papers on Economic Activity: Microeconomics*, 1996:2, pp. 133-188; and Ernst R. Berndt, Linda T. Bui, David H. Reiley and Glen L. Urban, "Information, Marketing and Pricing in the U.S. Anti-Ulcer Drug Market", *American Economic Review*, 85(2), May 1995, pp. 100-105.

215. With a host of factors known to affect the pricing path of a brand name, single source self-administered drug through its life cycle from launch to facing generic competition, the challenge facing Plaintiff's Expert is the following: How can it be determined that at any given point in time, it is one or more of the above factors that affected and were largely responsible for the price decisions made by defendant manufacturers during the product's life cycle, rather than Defendants' alleged AWP scheme to collect inflated prescription drug payments? Simply examining and recording larger differences in percent "spreads" between each AWPID drug and "drugs not subject to this Litigation" will not be sufficient to establish reliably that any differential "spread" is attributable solely, partly or not at all to the alleged AWP scheme to collect inflated prescription drug payments. Other factors could instead contribute to the differential "spread", to varying extents across drugs and time.

216. For a given AWPID drug, the choice of comparator "drugs not subject to this Litigation" will be critical. One possibility would be to choose as comparators one or more single source, branded self-administered drugs otherwise very similar to the AWPID drug but for its manufacturer's alleged pricing behavior. That is likely to raise a variety of medical and clinical issues requiring expertise from medical experts, and in any case, necessitates individualized drug-specific rather than class-wide treatment.

217. An alternative procedure that could attempt in a more sophisticated statistical manner to control for factors other than the manufacturer's alleged illegal behavior would involve use of multiple regression analysis, and what has come to be known as hedonic price analysis.²⁸³ Dr. Hartman refers to this somewhat briefly in his deposition, when asked about the

²⁸³ A discussion of the rationale underlying hedonic price analyses, and its history, is found in Ernst R. Berndt, "The Measurement of Quality Change: Constructing an Hedonic Price Index for Computers Using Multiple Regression Methods", ch. 4 in Ernst R. Berndt, *The Practice of Econometrics: Classic and Contemporary*, Reading MA: Addison-Wesley, Inc., 1991, pp. 102-149.

Kennett piano mover price fixing case in Massachusetts in which he had been retained as an expert for class certification purposes.²⁸⁴ In that deposition he refers to an article he jointly authored in the *Journal of Law, Economics, and Organization* that focused on the use of hedonic price analysis for certification and damage calculations in class action complaints.²⁸⁵

218. In his Rebuttal Declaration Dr. Hartman provides several examples of multiple regression equations he has estimated that could be interpreted as hedonic price regressions. Each of these regressions relates the actual acquisition prices of a drug (and whether these include all rebates is unclear) to its AWP. This is done for five single source branded self-administered drugs (although several such as Paxil, Coumadin and Claritin have generic competition by the end of the class time period). In each of these regressions, no comparisons are made with “drugs not subject to this Litigation”.²⁸⁶ It is therefore unclear to me at this time precisely how Dr. Hartman plans to proceed with hedonic price analysis, and at how aggregated a level that analysis will take place. A literature has also recently developed that critiques the usefulness of intertemporal hedonic regressions when the products are undergoing substantial quality improvement, and markets are rapidly changing. Clearly the markets for both self-administered and physician-administered drugs have undergone very substantial changes over

²⁸⁴ Deposition of Raymond S. Hartman, Ph.D., Boston, Massachusetts, October 7, 2004, Vol. 1, pp. 293-300.

²⁸⁵ I believe the referenced article is Raymond S. Hartman and Michael J. Doane, “The Use of Hedonic Analysis for Certification and Damage Calculations in Class Action Complaints”, *Journal of Law, Economics and Organization*, 3(2), Fall 1987, pp. 351-372. Two other articles by Dr. Hartman dealing with hedonic price analysis are: Raymond S. Hartman, “Product Quality and Market Efficiency: The Effect of Product Recalls on Resale Prices and Firm Valuation”, *Review of Economics and Statistics*, 69(2), May 1987, pp. 367-371; and Raymond S. Hartman, “The Use of Statistical Methods in Disparate Impact Cases: The Northern Mariana Islands Case,” *Litigation Economics Digest*, Publication of the National Association of Forensic Economics, Vol. 3, 1998, pp. 1-25.

²⁸⁶ *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, Attachment E, and pp. 47-49.

time. This can make assumptions of intertemporal stability in hedonic price analysis problematic.²⁸⁷

219. Professor Stephen Schondelmeyer and Marian Wrobel have pointed out that there are substantial acquisition cost differentials by class of trade (naming ten of them)²⁸⁸. This suggests that class of trade distinctions would need to be taken into account when examining the differential spreads between “artificially inflated” drugs and “drugs not subject to this Litigation”, by hedonic pricing analyses or other means. If the overall (rather than class of trade specific) spreads on the two sets of drugs are to be compared, to the extent class of trade acquisition differentials exist, the heterogeneity in distribution of each drug’s sales by class of trade will also need to be taken into account.

220. Another issue in choosing comparator drugs involves the time period. Evidence from a survey of a substantial number of employers’ health plans suggests that while in any given year there was non-trivial variation in the average discount off AWP obtained by health plans in their negotiated contracts with retailers and mail order services, over time this average discount has increased substantially. For brands, the annual 1995 through 2000 discount off AWP was 11.8%, 12.1%, 12.6%, 13.2%, 13.1% and 13.5%, respectively, while for mail order services the respective annual average discount off AWP was 15.0%, 14.6%, 16.6%, 17.1%, 17.4% and 18.5%.²⁸⁹ Although I do not provide references here, I believe both sides acknowledge this general time trend in discount off AWP between 1995 and 2000, and I expect they would acknowledge that this general trend has persisted if not accelerated since 2000. I

²⁸⁷ See, for example, Ariel Pakes, “A Reconsideration of Hedonic Price Indexes with an Application to PCs,” *American Economic Review*, 93(5), December 2003, pp. 1578-1596.

²⁸⁸ Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Cambridge, MA: Abt Associates Inc., August 30, 2004, pp. 9-16.

²⁸⁹ *The Takeda and Lilly Prescription Drug Benefit Cost and Plan Design Survey Report, 2001 Edition*, Tempe AZ: The Pharmacy Benefit Management Institute, Inc., Tables 9 and 10, p. 24. The tables also show that dispensing fees have typically been less for mail services than retail, and that the former have been falling more rapidly over time.

have cited evidence from the various OIG studies and the CBO earlier in this report; some of those studies are summarized in Attachment B.

221. Before discussing the issues in the choice of time frame when comparing spreads of drugs with “artificially inflated” prices to those “not subject to this Litigation”, I briefly document below the time trend in the distribution of discounts off-AWP for self-administered drugs. As is seen in Tables 2 and 3 below, for brands the distribution of discounts off AWP has drifted upward over time, with slightly more homogeneity in 2000 than in the earlier 1995-6 years, although this change is not substantial. For mail order drugs, the entire distribution of discounts off AWP is not only larger (“Mail service discounts vary more than retail, as an individual employer’s ability to get deep discounts depends on the demographics and utilization patterns of its patient population.”)²⁹⁰, but it appears also to have shifted over time, with a greater portion getting larger discounts.

Table 2

Percentage of Employers According to Retail Brand AWP Discount

Percentage of Respondents						
% off AWP	2000	1999	1998	1997	1996	1995
>15%	6%	6%	7%	3%	3%	0%
15%	20%	15%	15%	12%	10%	10%
14%	15%	10%	10%	6%	4%	4%
13%	40%	40%	36%	37%	33%	23%
12%	12%	20%	24%	26%	25%	26%
<12%	6%	8%	9%	17%	25%	37%

Source: *The Takeda and Lilly Prescription Drug Benefit Cost and Plan Design Survey Report, 2001 Edition*; Tempe, Arizona: The Pharmacy Benefit Management Institute, Inc., Table 11, p. 24.

²⁹⁰ *The Takeda and Lilly Prescription Drug Benefit Cost and Plan Design Survey Report, 2001 Edition*, Tempe, AZ: The Pharmacy Benefit Management Institute, Inc., Tables 11 and 12, p. 24.

Table 3

Percentage of Employers According to Mail Service Brand AWP Discount

Percentage of Respondents					
% off AWP	2000	1999	1998	1997	1996
>20%	19%	6%	5%	4%	5%
20%	19%	17%	9%	9%	5%
19%	19%	10%	7%	6%	4%
18%	15%	20%	21%	15%	11%
17%	14%	15%	19%	18%	11%
16%	9%	14%	12%	17%	16%
15%	7%	8%	13%	14%	17%
<15%	4%	10%	14%	18%	31%

Source: *The Takeda and Lilly Prescription Drug Benefit Cost and Plan Design Survey Report, 2001 Edition*; Tempe, Arizona: The Pharmacy Benefit Management Institute, Inc., Table 12, p. 24.

222. Dr. Hartman appears to suggest that in choosing comparator drugs and time periods, he may make only minimal use of the more recent data (since 1997), for two reasons. First, he argues that the market still has not digested recent information concerning the “artificially inflated” prices of AWPIDs:

“Given the slowness with which the information in these studies is assimilated by this industry, the findings of the 1997-2002 reports began to affect the understanding and expectations about drug pricing only in the last few years. The relationships between AWP and AAC found in these studies are too recent to have informed pricing expectations for most of the Class Period.”²⁹¹

While there may be merit to this argument in the context of physician-administered drugs where for reasons I discussed in Section V information flows have been impeded and obfuscated, this is unlikely to be the case in the context of competing PBMs managing purchases of self-administered drugs, where competition has been vigorous.

²⁹¹ Declaration of Raymond S. Hartman in Support of Plaintiffs’ Motion for Class Certification, September 3, 2004, Attachment D, p. 8.

223. A second argument advanced by Dr. Hartman regarding why he may focus primarily on pre-1997 data is that the post-1997 marketplace and its data have been “contaminated to an unknown extent” by the allegedly fraudulent pricing scheme:

“Given the allegations in this matter, the more recent (and larger) spreads reflect the AWP scheme to an unknown extent and are contaminated to an unknown degree for use as yardsticks for non-fraudulent pricing behavior”.²⁹²

If the number and sales proportion of the allegedly fraudulently priced AWPID drugs in this litigation constituted a substantial portion of the total US market, such contamination might be possible. At her tutorial before Judge Saris on December 6, 2004, however, Professor Meredith Rosenthal noted that although there are about 65,000 drugs on the market, “the use of AWP as a pricing mechanism for the vast majority of these drugs is not at issue in the AMCC or in this motion”. A footnote then elaborated as follows:

“The fact that for 99% of prescriptions AWP works and is not being challenged highlights why AWP is an accepted pricing benchmark and further highlights why there was no widespread knowledge of the abuse alleged in the AMCC.”²⁹³

It is not clear to me how Plaintiffs’ argument that AWP “works” for 99% of prescriptions squares with Dr. Hartman’s concern that post-1997 transactions of “drugs not subject to this Litigation” may have become contaminated by the allegedly fraudulent pricing scheme. In any case, as I understand it, while at this stage of the class certification process one assumes for the moment that the Plaintiffs’ claims are true, it is not general practice at this stage to make even further assumptions, not alleged in the AMCC, about spillovers from the 1% of drugs at issue.

224. There is one final analytical point I wish to make concerning Dr. Hartman’s proposed methodology. In what follows I will employ a minimum amount of algebra, using the

²⁹² Declaration of Raymond S. Hartman in Support of Plaintiffs’ Motion for Class Certification, September 3, 2004, Attachment D, p. 8.

²⁹³ Written Tutorial of Meredith Rosenthal, Ph.D., presented to Judge Patti B. Saris, December 6, 2004, pp. 2-3 and fn. 2, p. 3. Also see transcript of Day One – Tutorial – Evidentiary Hearing (Meredith Rosenthal testifying), pp. 47-48.

symbol “ Δ ” to denote “difference in”, so that, for example, “ Δ AWP” means “difference in AWP”. One definition of the spread for branded drug i at time t is: $\text{Spread}(i,t) = \text{AWP}(i,t) - \text{ASP}(i,t)$. Similarly, for branded drug j at time t , the spread is: $\text{Spread}(j,t) = \text{AWP}(j,t) - \text{ASP}(j,t)$. Suppose that between time periods t and $t+1$, the AWP on drug i increases, while ASP remains unchanged. Since revenues for a PBM under a typical contract with a third party payor increase formulaically with increases in AWP, other things equal, the PBM benefits from the $\Delta [\text{AWP}(i,t+1) - \text{AWP}(i,t)]$, and according to Plaintiffs’ theory, the PBM is incented as a result to “move market share” of this drug i , at the expense of the third party payors. Note also that in this case, the only reason the total spread has increased is because of the increase in AWP, not any decrease in ASP.

225. Now consider the case when for drug j , the AWP between periods t and $t+1$ does not change, but the ASP falls, thereby increasing the “spread” for drug j between time periods t and $t+1$. Notice that this has no revenue impact and therefore no effect on the incentives facing the PBM to move market share for drug j , because any change in revenues per prescription depends on a change in AWP, and in this instance there has been no change in AWP, even though there has been an increase in the spread.²⁹⁴

226. As I understand it, as part of his establishing class-wide injury and damages, Dr. Hartman proposes to compare spreads for various drugs over various time periods, without accounting for whether (or what proportion of) the differential spreads are due to changes in AWP vs. those due to changes in ASP. For the PBM, only those differential spreads attributable

²⁹⁴ I note in passing that Dr. Hartman believes that PBM rebates (which would affect their incentives) are not formulaically related to AWP. In his original Declaration, Dr. Hartman states: “The rebates paid to PBMs by the drug manufacturers were not formulaically related to AWP; they were additional financial incentives offered to PBMs to move market share.” *Declaration of Raymond S. Hartman In Support of Plaintiffs’ Motion for Class Certification*, September 3, 2004, fn. 28, p. 12. At his deposition on October 7, 2004, an errata sheet indicated that instead of “ drug manufacturers were not formulaically ” should be changed to “ drug manufacturers generally were not formulaically ”. See Exhibit 003 of the Deposition of Raymond S. Hartman, Vol. 1, October 7, 2004.

to changes or differences in AWP affect its incentives. Dr. Hartman has not addressed the issue of how he proposes to decompose differential spreads between the AWPID drugs being litigated here and those of “drugs not subject to this Litigation” into the set of transactions in which AWP was not changed while ASP was decreased (such transactions would appear to be excluded from the class, since PBMs’ incentives are unaffected in such situations) from those differential spread transactions attributable at least in part to increases in AWP. I note that decomposing the source of the differential spread is unnecessary in the context of purchases of generic drugs by retailers, or of both brand and generic mail order operations (including those owned and operated by PBMs), for in those cases the incentive to prescribe/dispense a particular drug increases with the size of the spread, regardless of its source. Finally, in the context of PBMs, decomposition of the source of any differences in spread could depend on the periodicity of the data; to date, most of these calculations have been done on a quarterly rather than annual basis.

227. In terms of data issues, I have not of course delved into the data sets employed by the various experts in this litigation. It goes without further elaboration that the sales data will need to exclude hospital sales, and that all rebates given by manufacturers to PBMs, providers and third party payors, need to be taken into account when calculating the ASP, and spreads based on the ASP. Moreover, since rebates are typically computed ex post, their temporal allocation needs care.

B. Physician-Administered Drugs

228. In Section V of this report I noted that expenditures on physician-administered drugs were likely only at most 11% of total prescription drug expenditures in 2002, and that this share was even smaller in earlier years. In part because of this relative importance, and aided enormously by accounting ambiguities concerning whether physician-administered drugs were

covered by the medical or drug benefit, as well as a J-code classification system that obfuscated true transactions prices and utilization, the quality of general information concerning actual prices for physician-administered services is likely to have been very poor. The information that did exist was not necessarily useful because of substantial likely heterogeneity in how third party payors tracked and contracted with providers, thereby making questionable any generalizability of the available information. Specialty pharmacies, like PBMs, appear to have a relatively diverse ownership (which I will not document here), but because of other informational flow impediments, and the relatively small importance of physician-administered drug expenditures, these benefits from diverse ownership have been more than offset by information flow problems involving physician-administered drugs.

229. The “high touch, high cost” characteristic of the physician-administered drugs also implies that the statistical variance from any sample of information could be very high, further jeopardizing the reliability of any single information source. When so little is known, it is not clear whether certain features are in fact “typical”. This will be a major challenge in considering the physician-administered portion of the class certification motion. Lack of appropriate information regarding injectables and other physician-administered drugs has also hindered effective public policy making.²⁹⁵

230. While this lack of information is gradually changing, and some payors such as TennCare have announced significant efforts in setting up systems to track specialty pharmacy utilization and prices more closely²⁹⁶, it will be a challenge in this litigation to track down

²⁹⁵ J. D. Kleinke, “Re-Naming and Re-Gaming: Medicare’s Doomed Attempt to Reform Reimbursement for Injectable Drugs,” *Health Affairs Web Exclusive*, 8 December 2004, 8 pp. Available online at <http://content.healthaffairs.org/cgi/content/full/hltaff.w4.561/DC1>, last accessed 1/12/05.

²⁹⁶ “TennCare Plans to Implement Maximum Allowable Cost for Specialty Rx Early in ‘04”, reprinted from the January 2004 issue of *Specialty Pharmacy News*, 4 pp. Available online at <http://www.aishhealth.com/DrugCosts/specialty/spntenncare.html>, last accessed 12/29/04. Also see related article regarding the Tennessee Blue Cross Blue Shield plan data improvement initiatives for specialty pharmaceuticals:

reliable information going back in time, either on a class-wide or on an individualized basis. An additional complication occurs because in those cases in which physician services and the prescribing/dispensing of physician-administered drugs are bundled into overall specialty physician fee schedules, such fee schedules will likely have geographical variations, as well as urban-rural differences, reflecting the underlying heterogeneity in real estate costs, wages for physician assistants and office staff, and the shortage/surplus supply situation among various specialties of physicians.²⁹⁷

231. Since the amount of expenditures involved in physician-administered drugs is relatively small, and its growth to more substantial proportion is only quite recent, it is not surprising that relatively little useful information and analysis has appeared in the public policy and academic literatures concerning pricing trends and patterns. For example, while it is true that there is a substantial literature documenting the pricing and time path of entry for generic drugs (witness the very long list of references provided by Dr. Hartman in footnote 62 of his Rebuttal Declaration)²⁹⁸, to the best of my knowledge, none of those cited papers deals with generic entry of injectables or other physician-administered drugs, and instead this literature focuses almost entirely on self-administered generic drugs.

232. In my own research and consulting, I have discussed generic entry patterns in the injectable and physician-administered drug sectors, but I cannot point to any relevant public domain literature. Without identifying specific companies and products, all I can say is that it is my perception that for injectables/physician-administered drugs, generic entry has typically not

"Tenn. Blues Choose Three Specialty Rx Vendors, Create Product List", reprinted from the January 2004 issue of Specialty Pharmacy News, 5 pp. Available online at <http://www.aishealth.com/DrugCosts/specialty/spnTennBlues.html>, last accessed 12/29/04.

²⁹⁷ This regional variability is discussed by Plaintiff's Expert Dr. Stephen W. Schondelmeyer, *Declaration of Stephen W. Schondelmeyer In Support of Plaintiff's Motion for Class Certification*, September 2, 2004, pp. 39-40.

²⁹⁸ *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, fn. 62, pp. 39-40.

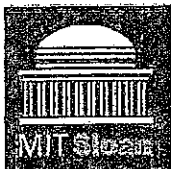
been as rapid and as extensive as it has with self-administered drugs. Moreover, for those injectable/physician-administered drugs not having an oral formulation as well (i.e., tablet or capsule versions), generic prices tend to fall more slowly and not as sharply as do generic self-administered drugs. Finally, in cases where there is both an oral and an injectable/physician-administered formulation of the identical active ingredient, following loss of patent protection, generic entry and pricing tend to be quite similar for self-administered and injectable/physician-administered drugs. These are the only generalizations I can comfortably make in terms of price and entry patterns for self-administered vs. physician-administered generic drugs, and even for these, for confidentiality reasons I am unable to provide explicit examples and references.

233. As I have indicated earlier in this report, it will be critical to be able to crosswalk easily between J-codes and NDC codes. At this point in time I cannot comment on how labor-intensive such a process will be, and the implications for class certification.

C. Final Comments

234. I have intentionally entitled this section of my report “Initial Observations on the Methodology Proposed by Dr. Hartman, and on Issues Regarding Class Certification”. The issues surrounding class certification are indeed complex, and I will continue to think and deliberate on them. I am available to discuss these matters further with the Court, should the Court deem that useful and appropriate.

Attachment A



CURRICULUM VITAE

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15 August 2004

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Education and Degrees:

B.A. (Honors) - 1968
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M.S. (1971) and Ph. D. (1972)
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The University of Wisconsin
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Major Field - Public Finance
Minor Fields - Demography,
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D. Phil., Honorary (1991)
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Ph.D. Thesis Title:

"The Economic Theory of Separability,
Substitution and Aggregation with an
Application to U.S. Manufacturing,
1929-1968"

Thesis Committee:

Laurits R. Christiansen, Chair
Arthur S. Goldberger
Charles E. Metcalf

Academic Awards:

Christ College Scholar, Valparaiso
University (1965-1968)

National Science Foundation Trainee
(1969-1970)

National Science Foundation Fellow
(1970-1971 and 1971-1972)

Most Cited Economist Under Age 40
in 1985

Journal of Economic Perspectives
Vol. 3, No.4, Fall 1989, p. 143, and
The Journal of Economic Education
Vol. 20, No.4 Fall 1989, p. 413.

Academic Awards (continued):

Elected Fellow, The Econometric Society, 1994

Distinguished Alumnus Award,
Valparaiso University, March 31, 1996

Excellence Award in Mental Health Policy and Economics Research, International Center of Mental Health Policy and Economics, Venice, Italy, March 2003 for article published in the March 2002 issue of The Journal of Mental Health Policy and Economics (see item #123 in publications listed below)

Listed in Who's Who in America

Current Positions:

Professor of Applied Economics, MIT
July 1, 1980 - present

Awarded Louis B. Seley Chaired
Professorship, February 1997

Director, National Bureau of
Economic Research, Program on
Productivity and Technological Change,
2000 – present

Adjunct Professor of Applied Economics,
Harvard Medical School, Division of Health
Care Policy and Research, 2001 - present

Previous Positions Held:

Research Economist
Office of Emergency Preparedness
Executive Office of the President
U.S. Government
Washington, D.C.
September 1971 - December 1972

Assistant Professor
Department of Economics
University of British Columbia
January 1973 - June 1976

**Previous Positions Held
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Associate Professor
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June 1976 - June 1980

Visiting Scholar
Department of Economics
Massachusetts Institute of Technology
July 1977 - June 1978

Visiting Scholar
Department of Economics
Stanford University
January - August 1985

Visiting Scholar
Harvard Business School
July 1990 - June 1991

Area Head, Economics, Finance and
Accounting, MIT Sloan School,
July 1992 through June 1995

Visiting Professor of Applied Economics
Harvard Medical School, Division of
Health Care Policy and Research
July 1996- June 1997

Other Professional Activities:

Elected Member and Member,
Executive Committee
Conference on Income and Wealth
National Bureau of Economic Research
1978 - present

Panel Resource Group Member
U.S. National Academy of Sciences
National Research Council
Committee on Nuclear and Alternative
Energy Systems (CONAES)
March 1976 - May 1978

Associate Editor of the Book Review
Section, Journal of The American
Statistical Association

1977 - 1981

Editorial Advisory Board

Resources and Energy

1979 - present

Member, Board of Editors

Energy Journal

1979 - 1988

**Other Professional Activities
(Continued):**

Associate Editor

Journal of Business Administration

1982 - present

Program Co-Chairman

Second Annual Meeting of the

International Association of Energy

Economists

Churchill College, Cambridge University

Cambridge, England, June 22-24 1980

Research Associate

National Bureau of Economic Research

Productivity and Technical Change

Program, and Health Care Program

1980 - present

Conference Co-Organizer (with Zvi

Griliches), NBER Workshop on

Measurement Issues, Investment, and

Productivity

Summer 1983, 1984, 1986 - 1999; with

others, 2000 - present

Associate Editor

Journal of Econometrics

April 1985 - February 1991

Associate Editor

Land Economics

April 1985 - February 1991

Member, Editorial Board

Journal of Economics and Management

**Other Professional Activities
(Continued):**

Strategy

February 1991 - December 1998

Member, Editorial Board

Economic Inquiry

September 1991 - present

Member

Dean's Advisory Council

College of Business Administration

Valparaiso University

Valparaiso, Indiana

September 1985 - present

Conference Co-Organizer (with William
Barnett and Halbert White)

Third Austin Symposium in Economics

University of Texas at Austin

May 22-23, 1986

Conference Co-Organizer (with
W.Erwin Diewert and Jack Triplett)

Jubilee Anniversary of the NBER

Conference on Research in Income
and Wealth

Washington, D.C., May 12-13, 1988

Editor

Journal of Productivity Analysis

1987 - 1991

Member, Special Advisory Panel

National Science Foundation

Science and Technology Centers, 1988

Conference Co-Organizer (with Timothy
Bresnahan, Zvi Griliches, and Marilyn

Manser), NBER Conference on Output

Measurement in the Service Sectors,

Charleston, South Carolina,

May 3-5 1990

Conference Co-Organizer (with Peter

Englund, Bengt-Christer Ysander and

Lennart Hjarmalsson), Productivity
Growth in the Service Sectors, Uppsala,
Sweden, May 22-24, 1991

Member, Advisory Panel
National Science Foundation
Measurement Methods and Data
Improvement Programs, 1990

**Other Professional Activities
(Continued):**

Economic Consultant and Academic
Affiliate
Analysis Group, Inc.
Cambridge, MA, 1985 - present

Member, Advisory Committee on
Service Statistics, Statistics Canada
Ottawa, Canada
December 1991 – February 2000

Member
Christ College, Alumni Advisory Board
Valparaiso University, Valparaiso, IN
January 1992 - present

Member, Committee of Visitors,
Program in Economics, National Science
Foundation
July 1992

Member, Research Consortium,
Financial Executives Research
Foundation, 1992 - 1995

Member, Editorial Board
Southern Economic Journal
July 1993 - present

Conference Co-Organizer (with Thomas
W. Malone and Laurence C. Rosenberg)
"The Productivity Impacts of Information
Technology Investments," Charleston,
South Carolina, November 11-13, 1993

Member, External Review Committee,
Pennsylvania State University,
Department of Economics,
March-April, 1994

Appointed Representative of the
American Economic Association to the
U.S. Census Bureau Advisory Committee
1996 – 2000; co-chairman, 1999 - 2000

Member and Chair, National Bureau of
Economic Research, Human Subjects
Investigation Review Board, 1998 - present

Member, National Academy of Sciences
Panel on the Conceptual, Measurement and
Other Statistical Issues in Developing Cost-
of-Living Indexes, 1999 - 2001

Member and Chair, Federal Economic
Statistics Advisory Committee, 2000 –
present

Member, American Economic Association,
Committee on Economic Statistics, 2002 –
present

Panel Review Member, National Science
Foundation, Program on Methodology,
Measurement and Statistics, Spring 2003 –
present.

Intermittent Detail to the U.S. Food and
Drug Administration, Office of the
Commissioner, 5600 Fishers Lane,
Rockville, MD 20857, October 1, 2003 –
June 30, 2004.

Editorial Board, RAND Forum for Health
Economics and Health Policy, March 2004
– present

Co-Director, MIT Biomedical Enterprise
Program, July 2004 - present

Publications (in chronological order)

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